

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

§ 405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* CMS gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

§ 405.2184 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply a sanction specified in § 405.2181(b), the following rules apply:

(a) CMS gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first \$100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a

full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in § 415.152 of this chapter who meet the requirements in § 415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic (RHC) means an entity that:

(1) Meets the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval.

(2) Has filed an agreement with CMS that meets the basic requirements described in § 405.2402 to provide RHC services under Medicare.

(3) Does not share space, staff, supplies, records, and other resources during RHC hours of operation with a private Medicare or Medicaid practice operated by the same physicians and non-physician practitioners working for the RHC. Operation of a multipurpose clinic with other types of health providers or suppliers is permissible subject to the provisions in paragraph (4) of this definition.

(4) Appropriately allocates and excludes from the RHC cost report the net non-RHC costs if it operates at a multipurpose location that involves the sharing of common space, medical support staff, or other physical resources with other health care providers or suppliers.

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395l, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003]

§ 405.2402 Basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services.* If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic.* If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement.* The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.